

"510(k) SUMMARY"
AS REQUIRED BY SECTION 807.92(c)

510(k) Owner's Name, Address, Telephone Number, Fax Number, Contact Person and Date Prepared.

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Date Prepared: September 8, 2013

Name of Device

- Trade Name: ZedView
- Common Name: Image Management Software
- Classification Name: Medical Image Management System, Product Code LLZ

Predicate Device

ZedView is substantially equivalent to the Meridian Technique Ltd. Orthoview™
(510(k) Accession Numbers: K032401 and K063327).

Device Description:

ZedView is a software package that provides computer-assisted 3D planning and evaluations using 2D image data in DICOM or other formats, for various pre-operative hip and knee surgical procedures. The software is composed of various modules as shown in Figure 1, below.

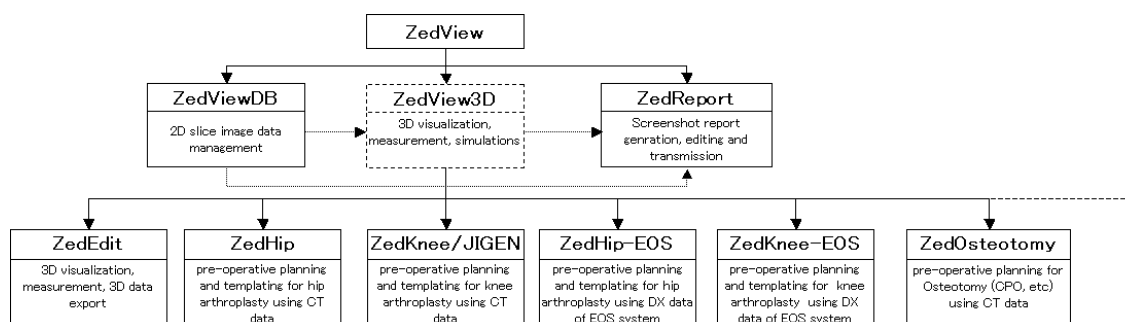


FIGURE 1

ZedView is intended to be used to assist qualified medical professionals to perform fast and effective pre-operative planning for various surgical procedures related to hip and knee by using 2D image data. The software is basically intended to be standalone, however some part of the software provides features for communicating with PACS servers to acquire the CT data of various patients or to upload planned projects, images or reports to the servers.

The software primarily provides import and storage of CT images of various patients in DICOM or other formats. Also, it provides a means of 3D templating of implants and positioning of fixation devices by calculating surgical parameters in simulated environments and performing 3D measurements on each pre-operative patient data, using 2D image viewing and manipulations, 3D visualizations and various MPR (Multi-Planar Reconstruction) functions.

The software also provides separate modules that support pre-operative planning of hip and knee arthroplasty for 2D digital X-ray images obtained with the EOS imaging system by providing quasi-3D templating, 3D measurement, etc. Besides the functional modules for artificial joint replacement surgeries, the software also provides a module that incorporates planning and evaluations for osteotomy (Curved Periacetabular Osteotomy etc.).

Intended Use

ZedView is intended to be used to assist qualified medical professionals to perform fast and effective pre-operative planning for various surgical procedures related to hip and knee by using 2D image data. The software is basically intended to be standalone, however some part of the software provides features for communicating with PACS servers to acquire the CT data of various patients or to upload planned projects, images or reports to the servers.

Predicate Device Comparison

The ZedView software is substantially equivalent to the Meridian Technique Ltd. OrthoviewTM Software (K032401 and K063327). (See Page 11-1 for the comparative analysis).

Performance Data: (Non-clinical Testing)

The Lexi ZedView Software was fully tested, verified and validated by Lexi as part of its own internal design control requirements using the test image data or real-life patient data. Verification and validation results confirm that the ZedView Software meets its requirements for intended use and its performance requirements.

Conclusions of non-clinical tests

The results of the non-clinical tests confirm that ZedView is as safe, as effective, and performs as well as or better than the predicates.

ZedView/OrthoView Comparative Analysis

Characteristic	Meridian Technique OrthoView (K032401)	Meridian Technique OrthoView (K063327)	Lexi ZedView
Computer	PC Workstation	Personal computer or Workstation/Server	Personal computer or Workstation
Operating System	Windows	Windows	Same
Availability of Device	Can be configured to be launched from within a workstation environment or as a standalone PC application for planning orthopedic procedures.	Same	Same
Source of images	Receive digital images from various sources (including PACS system)	Same	Same
Processing of data	Scaling of image facility	Same	Same
Superimposing digital Prosthetic Templates	Permits overlay of templates	Same	Same
Interactive positioning of template	Yes	Same	Same
Interactive sizing of template	Yes	Same	Same
Permits template rotation	Yes	Same	Same
Provides templating support from prosthetic manufacturers.	Yes	Same	Same
Permits automatic scaling	Yes	Same	Semi-automatic measurements
Pre-operative planning	Allowed	Same	Same
Osteotomy module	No	Yes	Yes
Patient contact	None	Same	Same
Control of life- sustaining devices	None	Same	Same
Human intervention for interpretation of	Required	Same	Same

Characteristic	Meridian Technique OrthoView (K032401)	Meridian Technique OrthoView (K063327)	Lexi ZedView
images			
Ability to add additional modules when available	Yes	Same	Same
Intended use	<p>The Orthoview™ system is designed with the intention that licensed medical professionals can access digitised medical X-Ray images in DICOM or other formats obtained from a variety of modalities such as PACS systems, X-Ray digitisers etc.</p> <p>This permits the review of such images and allows the overlay of digitised images of templates for prosthetic devices thereby providing an alternative to traditional means of optically viewing processed X-Ray films overlaid with the acetate templates of such prostheses supplied by the prosthetic manufacturer. Orthoview™ provides the means of recording, storing and retrieving the templating process steps performed by the licensed medical professional when assessing the optimum prosthetic device for a particular patient. The Orthoview™ system does not have any function such as image acquisition, image storage etc, this is the responsibility of the systems alongside which Orthoview™ operates. The Orthoview™ system does not specify the requirements for the prosthetic template - this is the responsibility of the prosthetic manufacturer.</p>	<p>Orthoview™ intended use is to enable a suitably licensed and qualified healthcare professional access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy modules and Trauma Templates are included to extend the range of functionality available to the healthcare professional.</p>	<p>ZedView is intended to be used to assist qualified medical professionals to perform fast and effective pre-operative planning for various surgical procedures related to hip and knee by using 2D image data. The software is basically intended to be standalone, however some part of the software provides features for communicating with PACS servers to acquire the CT data of various patients or to upload planned projects, images or reports to the servers.</p> <p>The software primarily provides import and storage of CT images of various patients in DICOM or other formats and provides a means of 3D templating of implants and positioning of fixation devices by calculating surgical parameters in simulated environments and performing 3D measurements on each pre-operative patient data using 2D image viewing and manipulations, 3D visualizations and various MPR (Multi-Planar Reconstruction) functions. The software also provides separate modules that support pre-operative planning of hip and knee arthroplasty for 2D digital X-ray images obtained with the EOS imaging system by providing quasi-3D templating, 3D measurement, etc.</p> <p>Besides the functional modules for artificial joint replacement surgeries, the software also provides a</p>

Characteristic	Meridian Technique OrthoView (K032401)	Meridian Technique OrthoView (K063327)	Lexi ZedView
			module that incorporates planning and evaluations for osteotomy (Curved Periacetabular Osteotomy etc.).
Indications for use	Orthoview™ is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic devices, for the purposes of choosing the nature and characteristics of the prosthetic device to be used when planning a potential surgical procedure.	Orthoview™ is indicated for use when a suitably licensed and qualified healthcare professional requires access to medical images with the intention of using such images, in conjunction with templates for prosthetic and fixation devices, for the purposes of choosing the nature and characteristics of the prosthetic/fixation device to be used when planning a potential surgical procedure. In addition, Trauma and Osteotomy modules and Trauma Templates are provided to extend the range of functionality available to healthcare professionals.	Pre-operative planning for various surgical procedures related to hip and knee like artificial joint replacement (3D templating of implants), osteotomy.

Discussion of Differences

Important Differences

1. Image format

OrthoView uses digital X-ray image data, ZedView provides pre-operative planning from CT sliced image data.

Discussion:

The CT image data provides more relevant information than the X-ray images, thus offers a better and precise pre-operative planning, while the intended use and the indications for use remain the same. Besides, ZedView also contains separate operational modules (ZedHip-EOS, ZedKnee-EOS) for providing pre-operative planning for hip and knee using the digital X-ray (DX modality) images from the EOS imaging systems.

2. Templating system

In contrast to the conventional 2D templating of OrthoView, ZedView provides CT-based 3D templating system. In addition to the template overlays in 2D cross-sectional images, the software allows user to place and register the 3D imported models of implants or fixation devices over the 3D reconstructed bone models and also provides 3D movement (translation, rotation) of the implants. In addition, ZedView offers visualization of bone models in various simulated post-operative positions and calculation of surgical parameters with respect to various coordinate systems.

Discussion:

The 3D templating system provides flexibility and extension of functionality by providing additional information (surgical parameters, range of motion analysis, etc.) for pre-operative planning than the 2D templating systems. Moreover, the 3D visualizations of bone and implant models help visualize elements that cannot be visualized in 2D, thus allowing for intuitive, effective and more accurate and precise planning.

3. Osteotomy operational module

In addition to the joint replacement modules, the Osteotomy module in ZedView also offers simulations, measurements, surgical parameters calculations, etc. in 3D.

Discussion:

Similar to the discussion in section 2 above, the extra information and the 3D visualization of simulated bone models allow for intuitive, effective and more accurate and precise planning.

Conclusion

While there are some differences between ZedView and its predicates, these differences are minor and do not affect device substantial equivalence. It has the same basic operational principles and technical characteristics as its predicates and it functions in the same manner. Additionally, it has the same indications for use and intended function and

use and performs as well as or better than its predicates. Therefore, Lexi believes that ZedView is substantially equivalent to the predicate devices cited within this submission.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

LEXI Co., Ltd.
% Mr. Edward Kroll
President
Spectre Solutions, Inc.
5905 Fawn Lane
CLEVELAND OH 44141

Re: K133022
Trade/Device Name: ZedView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 20, 2014
Received: February 21, 2014

Dear Mr. Kroll:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K133022

Device Name
ZedView

Indications for Use (Describe)

ZedView is indicated for pre-operative planning for various surgical procedures related to hip and knee, such as artificial joint replacement (3D templating of implants) and osteotomy.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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